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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,154	12/06/2001	Richard T. Skiffington	0656-008US6	1022

32665 7590 03/28/2005

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EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,154	SKIFFINGTON ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7,10,12,14,15,17-19,23,24,26 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *4 and 30* is/are allowed.

6)☒ Claim(s) *1,2,5-7,10,12,14,15,17-19,23,24 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *1/26/05*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The indicated allowability of claims 1, 2, 5-7, 10, 12, 14, 15, 17-19, 23 and 26 is withdrawn in view of the newly discovered reference(s) to Simpson et al.(EP 0 309 184). Rejections based on the newly cited reference(s) follow.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application (US Provisional Application No. 60/001,081, filed 12 July 1995) upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claim 30 of this application. With respect to claim 30, the instant claim language of claims 30 recites that the unit dose reagent chamber is for detection of alkaline phosphatase (AP) in a test sample. The specific reagents recited include one selected from the group consisting of i) a detergent-containing buffered solution to release alkaline phosphatase (AP) from the test sample into solution and ii) a reaction stopping solution having a pH of 8 to 11; and iii) a luciferin-luciferase or phosphatase substrate reagent. The disclosure of U.S. Provisional Application No. 60/001,081, filed 12 July 1995, discloses unit dose reagent chambers that include a cylinder having a one open end and an other opposite open end and a probe-puncturable membrane seal over the one end and the other end of the cylinder to form a sealed compartment. Provisional Application 60/001,081 also discloses that i) a microbial lysis solution and ATP stabilizer can be a reagent held in the sealed chamber; ii) a buffer optimized for luciferin-luciferase reaction can be a reagent held in the sealed chamber; or iii) luciferin-luciferase reagent tablet can be a reagent

held in the sealed chamber (See the first page of the disclosure and Figure 2). As a result, of all of the possible reagents listed in claim 30, U.S. Provisional Application 60/001,081 only provides support for "a luciferin-luciferase substrate reagent".

Note claims 1, 2, 4-7, 10, 12, 14, 15, 17-19, 23, 24 and 26 have benefit of the filing date of U.S. Provisional Application No. 60/007,585, filed 27 Nov. 1995, since these claims are supported by the disclosure of U.S. Provisional Application No. 60/007,585.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 2, 5-7, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein (US 4,770,853) in view of Simpson et al.(EP 0 309 184) and Rich et al.(US 3,666,631).

The reference of Bernstein discloses a unit dose reagent chamber for use in a test apparatus (See Figure 4). The unit dose reagent chamber includes a cylinder with opposite open ends both of which are sealed by probe-puncturable membranes (6,7,8).

With respect to claim 1, while the reference of Bernstein discloses the use of reagent compositions within the unit dose chambers, the reference does not disclose the use of reagents specific for the detection of adenosine triphosphate wherein the reagent is either a detergent-containing buffered solution to release adenosine triphosphate from a test sample or a luciferin-luciferase reagent.

While the preferred embodiment of the reference of Bernstein is directed to the performance of an immunoassay detection, the reference discloses that device is advantageous for assays that require multiple steps and require multiple reagents (See column 1, lines 13-28). The reference also discloses a number of types of reagents that can be used in the device including extraction reagent and lyophilized reagents (See column 3, lines 11-28).

The reference of Simpson et al. discloses a known for the detection of adenosine triphosphate that employs a plurality of steps and reagents. The reagents include a detergent-

containing buffered solution to release adenosine triphosphate from a test sample and a luciferin-luciferase reagent (See page 3, line 44, to page 4, line 15).

The reference of Rich et al. discloses that it is conventional in the art to provide reagents (92 and 94) for the detection of adenosine triphosphate in separate chambers that are separated by a frangible seal (82).

In view of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the adenosine triphosphate detection reagents as taught by the prior art references of Simpson et al. and Rich et al. within the test device structure as disclosed by the reference of Bernstein for the known and expected result of employing an alternative means recognized in the art for storing and performing a multiple step assay while providing the benefits disclosed by the reference of Bernstein when using the disclosed reagent holding system (See column 1, lines 4-28).

With respect to claim 2, the reference of Bernstein discloses the use of aluminum foil as a probe-puncturable membrane (See column 6, line 4).

With respect to claim 5, the combination of the references as discussed above would encompass the use of a unit dose chamber (15, 20, 27) in combination with a test apparatus (13) and a detergent-containing buffered solution to release adenosine triphosphate from a test sample and a luciferin-luciferase reagent.

With respect to claim 6, the test apparatus disclosed by the reference of Bernstein includes a longitudinally moveable probe (2,5) to puncture the membrane seals.

With respect to claim 7, the closed bottom end of the apparatus (13) of the reference of Bernstein is considered a test unit that includes one or more unit dose chambers.

With respect to claim 10, whether all of the reagents are positioned within the unit dose chambers or the last employed reagent is provided in the sealed bottom would have been obvious to one of ordinary skill in the art for the known and expected result of providing an alternative means recognized in the art for providing reagents within a sealed chamber which are intended to be sequentially contacted with a probe member. Providing all of the reagents in a unit dose chamber would allow the tube and probe member to be manufactured independent of the specific reagents employed. However, it also would have been obvious to provide the last reagent in the sealed bottom to avoid the extra cost and materials associated with the use of an additional unit dose chamber.

With respect to claim 12, the reference of Simpson et al. discloses the additional use of a buffer or neutralizing solution (See page 3, lines 55-56) when detecting adenosine triphosphate that has been released from a cell sample using a detergent solution.

7. Claims 10, 14, 15, 17-19, 23, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein (US 4,770,853) in view of Simpson et al.(EP 0 309 184) and Rich et al.(US 3,666,631) taken further in view of Matsumoto et al.(JP 7-59555).

The combination of the references of Bernstein, Simpson et al. and Rich et al. has been discussed above.

Claims 10 and 14 differ by reciting that the device includes a longitudinal housing and a separate transparent test unit attached to one end of the housing that includes the unit dose chambers.

The reference of Bernstein discloses that that lower portion or test unit (10) can be integral or separable from the housing (13) (See column 4, lines 65-68).

The reference of Matsumoto et al. discloses a known swab sample device construction that includes housing (3) and a separate test unit (1) that includes unit dose chamber (2) for separating reagents (X and 5) (See Figures 1-4).

In view of these teachings and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to provide a swab sample and reagent contacting configuration as suggested by the reference of Matsumoto et al. for the known and expected result of providing an art recognized equivalent for contacting a swab sampler with a plurality reagents.

With respect to claim 15, the reference of Bernstein discloses the use of aluminum foil as a probe-puncturable membrane (See column 6, line 4).

With respect to claim 17, the test unit (1) suggested by the disclosure of Matsumoto et al. is detachably secured to one end of the test apparatus (3).

With respect to claims 18 and 23, while the reference discloses the use of a cover (6) for the test unit, instant claim 18 differs by reciting that the test unit is sealed with a probe-puncturable membrane.

The reference of Matsumoto et al. discloses that the use of a probe-puncturable membrane (2a, 2b) is known in the art for sealing a chamber.

In view of this disclosure, it would have been obvious to one of ordinary skill in the art to seal the open end of the test unit using an additional probe-puncturable membrane in place of cover (6) for the known and expected result of providing an alternative means recognized in the

art for sealing a vessel. Use of the membrane would eliminate the need to remove cover (6) since probe device (4) would be capable of penetrating the membrane sealing the test unit.

With respect to claim 19, the reference of Simpson et al. discloses the additional use of a buffer or neutralizing solution (See page 3, lines 55-56) when detecting adenosine triphosphate that has been released from a cell sample using a detergent solution.

With respect to claims 24 and 26, the reference of Rich et al. discloses providing a luciferase/luciferin reagent in tablet form (94).

Allowable Subject Matter

8. Claims 4 and 30 are allowed.

9. The following is a statement of reasons for the indication of allowable subject matter:

Claims 4 and 30 would be allowable because the prior art of record fails to teach or fairly suggest the claimed ATP or AP testing device that includes pH indicator in combination with the claimed releasing solution, reaction stopping solution, or luciferin-luciferase or phosphatase substrate reagent to detect the ATP or AD of a test sample and wherein the pH indicator does not materially affect the basic characteristics of any of the above listed compositions.

Response to Arguments

10. With respect to the rejections of claims 8, 9, 21, 22, 25, 27-29 and 31-45, the rejections of record are no longer applicable since these claims have been cancelled in the response filed 1/6/2005.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William H. Beisner
Primary Examiner
Art Unit 1744

WHB